CROs : The best way to dynamize the pharmaceutical industry ?

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Déclaration

Ce travail de Bachelor est réalisé dans le cadre de l'examen final de la Haute école de gestion de Genève, en vue de l'obtention du titre «Bachelor en économie d'entreprise ».. L'étudiant accepte, le cas échéant, la clause de confidentialité. L'utilisation des conclusions et recommandations formulées dans le travail de Bachelor, sans préjuger de leur valeur, n'engage ni la responsabilité de l'auteur, ni celle du conseiller au travail de Bachelor, du juré et de la HEG.

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Fait à Genève, le 31 mai 2013

Jean-Philippe LUTZ

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Executive Summary

This Bachelor's Project examines some of the main obstacles opposing the pharmaceutical industry today. They may be identified as follow:

1. Low shareholder or stakeholder value delivery
2. Low growth environment
3. Stagnating R&D productivity
4. Growing risk and damaged trust

I postulate that the pharmaceutical industry has a substantial chance to redress itself in the eyes of shareholders or stakeholders, succeeding to surface in the current unsatisfactory business climate.

Vegetating Occidental markets, shared with growing Emerging Markets, will alter both the formula as well as the wishes of the industry. The growth of Emerging Markets will generate and increase sales, though will also lead to a reduction in margins.

R&D productivity has been substandard in the last years, and the dynamics will need to change, for the industry to carry on with extensive growth. The approval rates, granted by the FDA, have provoked a great number of molecules to fail in the quest of reaching the market.

Several risks have been rising and disturbing the evolution of the pharmaceuticals. These are namely scientific, political, legal, and image-related risks. These menaces have brought pharmaceuticals to invest their time and money on matters that could have been mitigated by means of additional testing or deepened market research.

I believe that, throughout the course of this paper, a number of solutions may be identified to deliver new dynamics to this suffering industry. Since pharmaceuticals aspire to reduce costs and to accelerate their drug development process, they may request the assistance of CROs, specialized in R&D activities. This will lead to an enhancement of pipelines, an improvement in R&D productivity, an increase in savings, and a provision to the pharmaceuticals of additional solutions in their pursuit of delivering medication to the markets in a timely manner.

The industry will respond positively to their issues with the help of innovative solutions that CROs propose. I am of the opinion that collaboration between a pharmaceutical and a CRO may only be a positive one, because it would accommodate the alignment of expertise, qualified staff, and facilities for a structure that is currently in dire need of these.

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Introduction

The pharmaceutical industry is an economical branch comprised of a great number of activities divided into three main pillars: the initial molecular phase, the intermediary analytical stage, and the final production and commercialization of the licensed drug.

This multi-billion dollar business involves a flurry of multinational pharmaceuticals companies, biotechnological companies and other service companies, which need to bring their final product to the market in a shorter period of time. Therefore, this is synonymous to actually earning in revenue, and gaining more market shares to maintain sustainability as a player in said industry.

In drug development, it is known that one of the major costs comes from the R&D sector. This implies the need for massive investments in infrastructures, such as specific machinery, qualified work force, and time for clinical trials to be carried out.

Since the 1990's there has been a rising demand by the drug industry to use "Contract Research Organizations" more commonly known as CROs. These service companies provide a wide range of outsourced support products to pharmaceuticals, biotechnology, food producing companies, cigarette manufacturers, and medical device producers, among others. CROs primarily provide their services on a contract basis, which means that any given pharmaceutical company may hire a different CRO per drug developed.

May we consider a CRO as an essential factor in the life of a pharmaceutical company? Furthermore, at what extent are CROs implicated in clinical trials? The answers may lie in the provision of both quality services and strategic partnerships; thus, enhancing the dynamics of each drug being developed.

The focal point of this thesis is to present a clear picture on how CROs work, and the potential they may encompass upon partnering with pharmaceuticals. Indeed, some notable factors will be outlined, elucidating strategy alignments between a client and a CRO.

The initial chapter of this proposal displays the pharmaceutical industry and its identified hardships. The recognized challenges involve value delivery for shareholders or stakeholders, poor growth environment, deteriorating R&D output, increasing risks, and loss of trust.

This shall be followed by a macro-environment analysis of the pharmaceutical industry, employing tools such as the PESTEL and Michael Porter's five forces. The external evaluation will aid in the construction of the internal analysis shaped by a SWOT, which enumerates the strengths, weaknesses, opportunities, and threats that affect the activities corresponding to drug development.

In the next chapter, we will obtain a clearer vision on CROs and their market. This will provide us with a better understanding on the various factors that differentiate said entities, such as: the influence of company size, the geographic presence, the service quality, the therapeutic differentiator, and, lastly, the effect of pricing.

The next item in this paper will refer to the CRO strategy. This will be comprised of the same types of analysis as the ones utilized for the pharmaceutical industry, which translates into an external and an internal examination of this business.

The last chapter of this document is focused on knowing more about Covance, an influential player in the CRO world. This section exhibits an idea of the company, pertinent facts and figures, its business strategy, and the competitors on this market.

The conclusion and recommendation segment highlights both the respective findings, as well as the provided solutions. This may be significant for the pharmaceutical and CRO industries to progress in a prosperous way.

1. Pharmaceutical Market Overview

The pharmaceutical market is a fragmented market with a great number of companies having no more than 10 percent of the market. In the past years, companies in this industry have been slowing down the pace of their businesses due to factors such as:

1. Low shareholder or stakeholder value delivery
2. Low growth environment
3. Stagnating R&D productivity
4. Growing risk and damaged trust

1.1 Low shareholder or stakeholder value delivery

Looking closely at the shareholder or stakeholder value, we can identify more negative factors than positive ones.

Among the positive aspects, we may see potential in strong growth from the Emerging Markets in Asian and Latin American countries. The aforementioned markets are targets to suffer an increase in their sales volume, but with lower margins. Indeed, pharmaceuticals cannot sell their products at the same prices as in the Western world due to lower incomes.

If we look at Occidental populations, we may notice that they are undeniably aging. Said factor can only enhance the business of pharmaceuticals, as they are important medicine consumers.

On the other hand, the negative factors striking the industry are numerous. We may begin highlighting the increasing speed and intensity of product competition. We have enumerable drugs that serve the same purpose, albeit having been produced by different pharmaceuticals.

Increasing government rebates in the U.S.A also have a negative effect on the pharmaceuticals, resulting in a minimization of their margins. Since the U.S Government intends to cut costs in its Healthcare budget, pharmaceuticals are forced to reduce their prices. Hence, margins melt as well.

The loss of revenue due to patent expirations lowers the income of the pharmaceuticals; therefore, becomes a driver for the fierce generic markets.

Higher regulatory hurdles lead to uncertainty in the testing and commercializing of a molecule or a compound. Thus the FDA[1] grants lower approval rates.

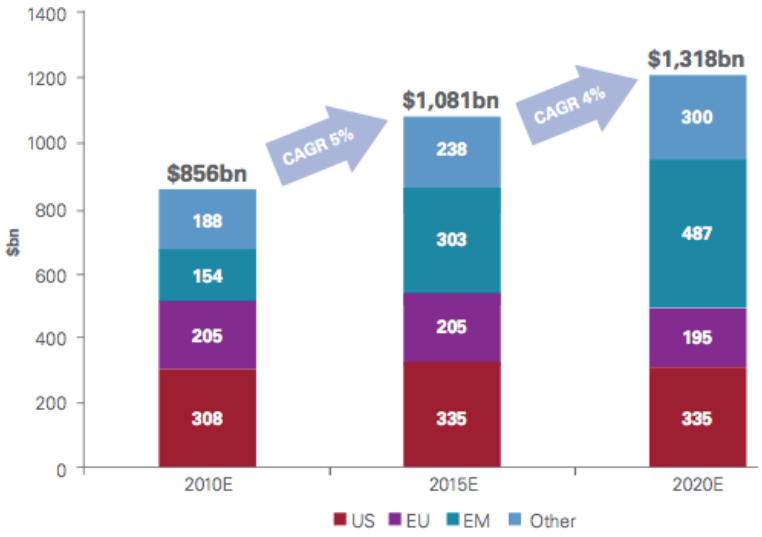
1.2 Low growth environment

As per KPMG's European Sector leader for the pharmaceutical industry, Chris Stirling, the potential growth prospect for the industry would be of approximately 3 to 6 percent growth from 2010 to 2015. This would notably be the case because of factors such as patent expiration bringing down product revenue in Western markets. Patent expirations are, in most cases, synonymous to growth for generic producing companies.

The possible growth for the pharmaceuticals may arrive by means of the Emerging Markets. According to KPMG's figures, growth in the Emerging Markets could climb from 12 percent in 2005 to reach 28 percent in 2015.

Figure 1

Pharmaceutical Industry 2010 to 2020 by Major Geographic Market



Source: 2010,2015 IMS Health; 2020 KPMG estimates

Figure 1 displays the dynamics of working in the Emerging Markets with a compound annual growth of 5 percent from 2010 to 2015. This may be attributed to the massive expansion in these markets. This enhances the annualized gain of

[1] FDA- Food and Drug Administration

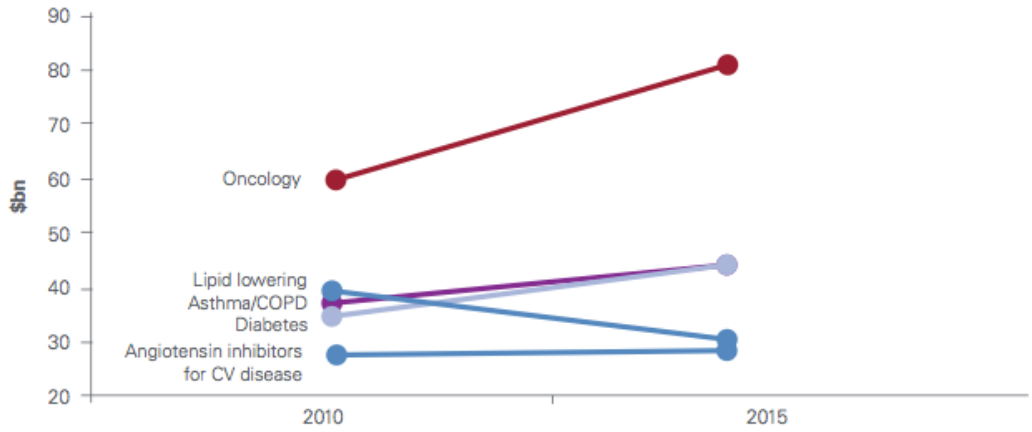
investments over the five-year period. Growth will be as spectacular and important from 2015 to 2020, as per the respective forecasts prepared by KPMG.

However, evolving policy changes in American, European, and Asian countries will minimize growth in these areas, as countries tend to spend more efficiently on healthcare to reduce growing budget deficits.

According to the IMS Health, information, service and technology provider for the healthcare industry, the following therapeutic classes are drivers for brand growth from 2010 to 2015.

Figure 2

Forcasted Therapeutic Class growth from 2010 to 2015



Source: The Global Use of Medicines: Outlook Through 2015. IMS institute for Healthcare informatics May 2011

Figure 2 demonstrates that the main therapeutic area to focus on for growth would be oncology. This therapeutic area could rise from 5 to 8 percent annually, which represents 75-80 billion U.S. dollars from 2010 to 2015.

Moreover, the second therapeutic area to drive growth would be diabetes. The forecasted growth in this area would be of about 4 to 7 percent per year, which is equivalent to 43 to 48 billion U.S. dollars.

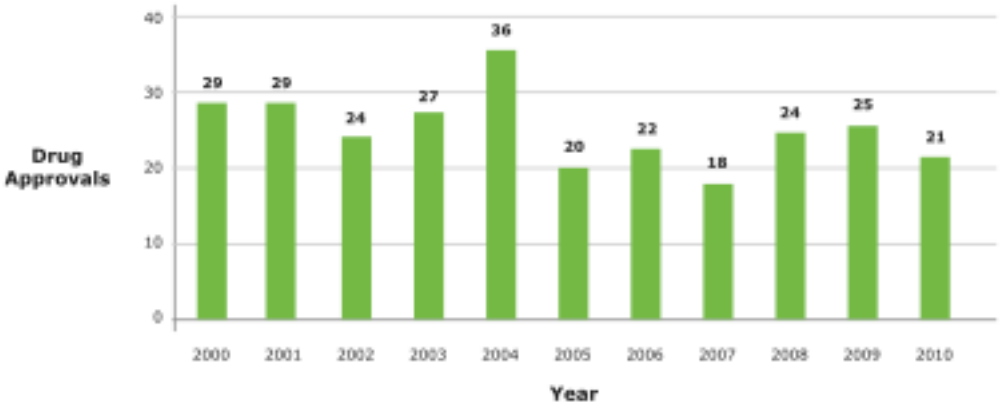
Furthermore, autoimmune diseases annual growth is expected to rise 6 percent a year to hit 30 billion U.S. dollars on an annual basis. Lastly, we can also expect continual growth from asthma, cardiovascular diseases, and biological therapies. These are estimated at 5 percent growth per annum.

1.3 Stagnating R&D productivity

In relation to Research and Development, the productivity has been minimal due to low application filing in the industry. The decreased rate of drug approvals by the FDA leads to a lower number of medicines that goes through the clinical testing process. We may perceive that bringing fewer drugs to the markets is synonymous to less growth in the industry.

Figure 3

Number of Applications for New Medical Entities to FDA



Source: FDA: http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/UCM192786.pdf

Figure 3 displays the fluctuating trend, throughout the last twelve years, of the number of applications for new medical entities. We may point out, in 2010, the second lowest approval rate in the decade. However, 2011 and 2012 may lead to better productivity due to the expansion of the biotechnological industry and the growing partnerships between these ones and large pharmaceuticals in the quest for new molecules.

1.4 Growing risk and damaged trust

Much like any other industry, the pharmaceutical business encounters different risks that may directly or indirectly affect their business. According to the assessment carried out by KPMG, different impacts may possibly lead to increasing the risks, and tarnishing the trust of different stakeholders

The pharmaceutical organizations have to react upon the risks detailed as follow:

1. Scientific risk
2. Political risk
3. Legal risk
4. Image related risk

1.4.1 Scientific risk

As per the risk survey completed by KPMG, only five major players out of thirteen had provided assurance to their board about quality, competitiveness, and integrity of R&D and scientific activities. This, in fact, comes as quite as surprise, as it demonstrates minimal transparency in reference to this type of risk. However, if we were to conduct a survey including a larger panel of companies, said research would probably be inferior to the alleged 38 percent from KPMG's study.

1.4.2 Political risk

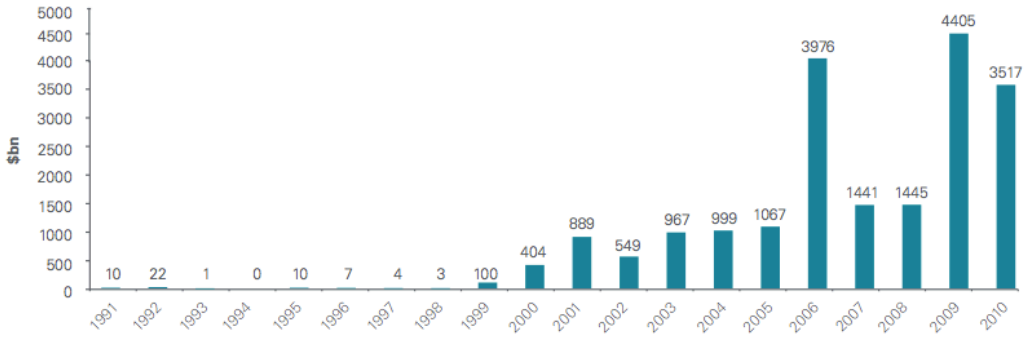
Political risk, especially in the Western world, will be a portion of process planning. To avoid any political downturns, pharmaceuticals are compelled to remain close to government thinking. Consequently, this is critical in securing a continuous business evolution in the Occidental world, and towards future positioning in the Emerging Markets.

1.4.3 Legal risk

Companies have compiled a wide range of risk management tools, and have implemented Board Audit Committees in pursuance of the minimization of this type of risk. This is due to an increasing number of lawsuits that have been filed against pharmaceuticals. Figure 4 hereunder displays the considerable increase in lawsuit allegations against pharmaceuticals. This phenomenon has been increasing since the year 2000.

Figure 4

Value of Pharmaceutical Settlements with US State and Federal Government from 1991-2010



Source: Public citizen: Value of Pharmaceutical Settlements with US and Federal Government 1991-2010

Poor manufacturing practices or off-label promotions[2] that pharmaceuticals have made use of may explain the abovementioned phenomenon. For instance, Schering-Plough was fined 500 million U.S dollars because of poor manufacturing practices for their Claritin product.

In 2009, Pfizer had to pay one of the largest fines – amounting to 2.3 billion U.S dollars – due to an off-label promotion that was judged as "False Claim Act"[3] for the following 4 products: Bextra, Geodon, Zyvox, and Lyrica.

1.4.4 Image related risk

In order to gain an improved image, the firms in this industry need to reverse the negative trend they are undergoing. This could start by winning back the trust and confidence on a consumer's perspective. Furthermore, they may also have to demonstrate more implication with government related activities. The ascertainment appears to indicate that pharmaceuticals place their commercial goals above the respective interests of governments, patients, and prescribers. This will have to change for the industry's embellishment to come to pass.

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[2] practice of prescribing an unapproved indication, age group, or dosage

[3] An American federal law that imposes liability to a person or a company who defraud governmental programs

2. The sponsor's strategy

The sponsor[4] is known as the client, and, in most cases, a pharmaceutical company. The main goals of the firm are to be sustainable, and to gain in market shares. In order for this to happen, the company has to clearly define an objective, a mission, and a vision to stand its ground as an influential player in this exigent market.

2.1 Macro Environment analysis (PESTEL)

It is essential for any company to analyze its external environment to be familiar with the different stakeholders that may influence a product or a company. The method that will be employed to evaluate this is denominated as a PESTEL (Political, Economic, Social, Technological, Environmental and Legal) analysis.

2.1.1 Political Factors

Political pressure in this industry is severe. Western countries, such as the U.S.A, demand more affordable medication, which heightens the difficulties in the business. Furthermore, budget allocations for healthcare are diminishing, as Western populations are aging.

Another fact that may result in profit reduction, in the long run, is the minimization of the terms by which patents can be maintained into force (patent lengths). A patent is valid from the moment a molecule is found, until twenty years thereafter. This is why pharmaceuticals struggle to accelerate the entire drug development process5 until the commercializing phase.

2.1.2 Economic Factors

Pharmaceuticals are constantly under pressure to refill their drug pipelines[6] because R&D returns are slumping below the cost of capital. Hence, costs are aggrandizing, without a guarantee of a moneymaking product to balance said increase. In point of fact, the number of molecules being developed is high, but the new molecules actually reaching the market remain poor.

[4] accountable for the realisation of the project.

[5] The process of bringing in new drugs

[6] Potential drug candidates that are under discovery or development

As stated earlier, the Emerging Markets represent one key to success in the attainment of increasing income. On the other hand, return margins remain lower than prices established in Western countries.

2.1.3 Social Factors

Pharmaceuticals should keep in mind that Western populations are aging, and that the treatments they propose are too costly. Furthermore, and in the Eastern countries, we may witness younger populations that barely generate enough income to afford their medications.

2.1.4 Technological Factors

R&D costs, in the industry at hand, are heavier as both drug development as well as safety[7] practices tend to lead to longer periods. Furthermore, companies tend to outsource their clinical trial[8] activities in order to avoid climbing costs, and to hasten the testing process.

We may also underline the lack of investment in IT infrastructures and social media. Pharmaceuticals work with antiquated tools, such as faxes and other means of communication, as opposed to investing in new technologies to boost more efficient channels that may provide countless advantages in marketing and sales.example

2.1.5 Environmental Factors

The use of certain chemicals, as well as the disposal of other chemicals waste, may result in heavy fines or penalties. This is the reason for which pharmaceuticals are forced to be highly aware of their internal processes, in regards to waste management.

2.1.6 Legal factors

In drug development, the main regulators are the FDA in the U.S.A and the EMEA[9] in Europe. These institutions require long timelines for drugs to be approved, by cause of a myriad of administrative and bureaucratic steps, necessary accreditations, and required testing.

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[7] involving collection, detection, assessment, monitoring, and prevention of opposing effects

[8] set of tests in drug development that produce efficacy data about drug reactions and adverse effects

[9] European Medicines Agency

Other legal factors that have been affecting the industry are the various lawsuits filed against the pharmaceuticals. Certainly, complaints pursued against these firms have provoked multi-million U.S. dollars fines.

2.2 External Environment analysis (Michael Porter's 5 Forces)

Another tool that will help the macro-environment analysis would be the five forces enumerated by Michael Porter. This will provide us with an improved understanding of both the intensity in the pharmaceutical market, as well as the attractiveness in terms of profitability.

2.2.1 Threats of new entrants

In this industry, the barriers that induce difficulties in entering the market are high, mainly due to large investments. Indeed, companies that are already positioned in this market possess an economy of scales (in manufacturing, R&D, and Sales Marketing). Moreover, pharmaceuticals have known products in different therapeutic areas, in which they have been able to build brands. Additionally, they have patents for drugs, and they sponsor healthcare programs in several countries. Performing distribution channels also accentuate high barriers at market entry.

2.2.2 Threat of substitutes

Threats are inevitable in any business, though in this industry, we may consider them to be moderate. However, the substitutes indicated as follow, are be taken into account:

- Medical devices
- Alternative therapies (homeopathic remedies, herbal/natural medicines)
- Surgery
- Generics (when patents have expired)

2.2.3 Rivalry among established firms

The competition in this market is tough, and firms are indebted to gain advantages over each other. We may perceive this market as a fragmented one, due to the fierceness in competition; thus, conferring on the market leaders around 10 percent of market shares.

An additional factor that plays a major role is product differentiation. Companies may have similar products that are aimed towards the remedy of the same illnesses, but

make use of different therapeutic components. In addition, aggressive pricing accentuates rivalry amongst these firms. In the case of large groups, rivalry may also appear in advertisement battles, which foregrounds market positioning.

2.2.4 Negotiating power of buyers

From the buyer's perspective, we may think that the bargaining power is moderate. On one hand, we have hospitals and health organizations that hold a high power of negotiation. On the other, we have the patients that possess a low power of negotiation. Moreover, governments are not to be neglected. They possess the prerogative in relation with the establishment of prices, as they may impose pharmaceuticals to lower their prices should said firms desire to integrate the different local markets.

2.2.5 Bargaining power of suppliers

On the contractor's standpoint, the power of negotiation remains minimal. By and large, biotechnology firms may be considered as major suppliers, since they provide the initial molecules, and feed the pipelines of the pharmaceuticals. On the other hand, they require the financing brought in by the sponsor.

On the procurement perspective, the bargaining power bides low. The leveraging power of the pharmaceuticals provides them with the opportunity to find the most adequate supplier for whatsoever needs they might have; therefore, resulting in a more cost efficient supply chain.

Lastly, we may expect a low negotiation power of CROs. Actually, for service companies to rake in more business, they would have to comply with the pharmaceuticals by providing them with the best service, at the best price.

2.3 Micro Environment analysis

The micro environment analysis will be established by means of a SWOT analysis. Detailed in this table are the elements that point out the Strengths, Weaknesses, Opportunities, and Threats that affect the pharmaceutical companies.

Table 1

Pharmaceutical SWOT Analysis

STRENGTH	WEAKNESS
Big structure companies Blockbusters Global geographic locations Worldwide positioning	Length to develop a drug Low pipelines Heavy dependency of Blockbuster drugs Poor IT infrastructures Low drug approval rate Patent expirations
OPPORTUNITIES	**THREATS**
Aging populations in the West Emerging Markets Mergers and Acquisitions Enhancement in Social Media Changing IT landscape Increase the use of CRO's/CMO's	Healthcare programs Intensity of product competition Loss of revenue due to patent expiration Ferocity of generic competition Declining R&D productivity Increasing legal settlements Increasing regulatory requirements Growing safety requirements

2.3.1 Strenghts

As a result of the given SWOT analysis, we may realize that companies that have a superior structure boost the strengths of this industry. Likewise, this gives them the occasion to use the economy of scales at a production level, for example.

It is apparent that companies in this business rely on blockbuster drugs, which individually account for revenue of over one billion U.S. dollars per annum. These consist in popular products that will enhance growth for these corporations.

In most cases, these companies boast of a global geographic presence, with local area offices. Ergo, this provides them with the upper hand in regards with local market research and local needs. The presence in diverse countries indeed provides these corporations with a worldwide positioning for their different therapeutic areas. Therefore, they may vend their well-known products, on a worldwide scale.

2.3.2 Weaknesses

A main weakness that a pharmaceutical company cannot avoid is the length of time invested in the development process a drug. The drug development process can be characterized as both extensive as well as intricate. Said process entails an average stretch of fifteen years for the drugs to be developed from the molecule phase, until it finally reaches the market.

Another weakness that affects the firms in this industry is the low drug approval rate granted by the FDA, which is of approximately 0,5 percent[10]. This consequence directly affects the income of drug making firms. Thus, pharmaceuticals possess lower potential to commercialize and earn revenue as a result of their investments.

Another important challenge pharmaceuticals face refers to patent expirations. A patent lasts twenty years, once the molecule has been discovery. This is why pharmaceuticals are forced to accelerate their R&D process, as only upon approval may the firms begin commercializing their drugs until expiry.

As underlined by KPMG, the use of technology in this industry is relatively low. Pharmaceuticals will have to evolve in their IT infrastructures by dedicating more investments to this cause. The difficulty, in this regard, would be the assembly of an infrastructure that is secure, effective, reliable, and cost-efficient.

[10] There were 9737 molecules in development but only 21 were approved in 2010. Aptuit whitepaper

2.3.3 Opportunities

The opportunities are significant for the pharmaceuticals, as they are the main driver for growth in the business. The aging populations, as well as the apparition of unfamiliar sicknesses, have given pharmaceuticals room for the creation of new business opportunities.

As underlined earlier, the Emerging Markets are the most apparent sources to develop business opportunities. China and India are the world's most populated countries, and a goldmine for business to evolve. Nevertheless, Brazil and Russia are key countries as well, with a middle class that is gradually rising.

Mergers and Acquisitions may also be important opportunities for pharmaceuticals. Mergers can help in strengthening a position in a market. This could lead to pharmaceutical diversification in different therapeutic areas in which they had previously lacked knowledge. Additionally, this comes to be a new source to feed pipelines. Furthermore, economy of scales may arise to reduce costs at different levels of the supply chain.

On the acquisition angle, we encounter the same principle, which reveals a trend where pharmaceuticals have to proceed with the acquisition of biotechnology companies. They do this to add new molecules to their pipelines, and to attract new talent they lacked.

To illustrate this, we may use the case of a big pharmaceuticals company such as Pfizer, who purchased Wyeth in 2008-2009. This acquisition provided Pfizer both with larger pipelines to work on, as well as with more diversified their portfolios with new vaccines, for instance. This deepened internal knowledge had solidified their market position, and had intensified revenue and earnings per share.

Compared to other industries, we may observe that the use of social media in the pharmaceutical industry is low. Social media may be an aspect that pharmaceuticals could use to grow. This communication canal provides awareness to the consumers on the new products, and may also give the firms valuable feedback from the end user. Furthermore, said social media tools, such as Facebook, Twitter, etc., could be used by these firms to improve on sales and marketing strategies for example.

In reference to the IT landscape, we can see that new technologies have appeared, and could improve the way pharmaceuticals work and communicate with their stakeholders. Since the recent boom of smartphones and tablets, pharmaceuticals could have applications created, aimed at the improvement of data transmission, for instance. However, this opportunity is time consuming and costly to implement for the meantime.

Throughout the cycle of drug development, pharmaceuticals will need to outsource some of their activities to specialized firms in order to reduce in R&D costs and manufacturing costs. The favorable circumstances of working with Contract Research Organizations could be a breath of success in the whole process of drug development. On the manufacturing side, they could use the aid of Contract Manufacturing Organizations » to improve cost control related to the production process.

2.3.4 Threats

The threats for drug development companies are numerous, and are, consequently, complex to overcome. Pharmaceuticals will have to strive in overcoming these challenges.

Firstly, there exist countries that are implementing healthcare programs to ensure better access to quality health treatments. The issue, in this case, is government. They are trying to lower healthcare cost, which directly affects the price of medication. Moreover, this is a challenge that pharmaceuticals may hardly overcome, unless they decide to reduce their prices. The good relationship with governments becomes fundamental to influence certain decisions in the matter of healthcare agreements.

Concerning the intensity of product competition, it can be considered a major threat as there is great pressure on pricing. Moreover, ferocious advertizing battles are set between competitors to catch the client's attention. Furthermore, the differenciation factors between products are small.

Upon expiration of a patent, the company that developed the drug is in a phase where his revenues drop due to the accessibility of his exclusive product. This brings in the generic companies that produce cheaper medication, and that create ferocious price competition in the drug industry. Additionally, the pharmaceutical company that developed the medicine may only rely on its brand notoriety and reputation.

R&D productivity,as seen this past year, has been diminishing. Pipelines in the last decade have been slowed down, notably due to slumping productivity. Looking at the future, this R&D productivity may shift in the right way. As per Deloitte's European R&D advisory practice head, 2011 has shown positive signs in regards to late stage productivity, which involves commercializing medication.

The main forcus may lie on an internal rate of return from R&D to cover the cost of capital estimated at 7 percent in average. In 2011, the internal return rate was approximately 7.2 percent.

As told earlier, increasing legal settlements have been polluting the pharmaceutical business. This defiance is due to a lack of compliance by the pharmaceuticals. This may be a result of naivety and carelessness by drug producers. The impact on the business is considerable, as it darkens the image of the companies from the client’s view and it increases legal settlement costs ranging from a couple of millions of U.S. dollars rising to billions of U.S. dollars.

Regulatory requirements in this industry are severe as they are demanding more and more in regards to clinical testing. Furthermore, this implicates more time and money spent.

In line with these regulatory requirements are the safety requirements. These have been enforced due to unexpected adverse events raised by several commercialized drugs. As a result of these gaps, the FDA established tougher rules in regards to patient safety, which demand more testing to be performed.

3. Contract Research Organization market overview

The CRO industry is also considered a very fragmented market due to a large number of operating companies. These firms operate on a contract basis. Moreover, several CRO's may work on one specific project. This business may be categorized by size, by geographic presence, by quality of services, by therapeutic areas, and by price.

3.1 Impact by size

The size of the CRO defines its capacity to perform a certain number of tests. Furthermore, we may take into account the qualification of its workforce, and the gained notoriety throughout the previous years.

3.1.1 Large CROs

These CROs would have more services to offer the client, going from local services to a more global approach in regards to early development[11] up to late stage[12] clinical trials. Furthermore they are involved in big scale drug development trials going from the early stages of molecule development up to the fourth phase of drug development, which is the commercializing of the medicine. These companies usually cover most, if not all-therapeutic areas for growing business.

3.1.2 Medium CROs

A medium size CRO would tend to offer slightly less services, with less workforce than a large size CRO. However, the fact of being smaller gives more flexibility to sponsors on business offerings. Additionally, they are still players demonstrating a certain depth in relations to experience and knowledge. Furthermore, they cover most therapeutic areas, but specialize in a few.

3.1.3 Small CROs

A small CRO generally works in a very small geographic perimeter offering more tailor made services, since they do not have the capacity to provide, as many services as larger companies. These firms are mostly specialized in one or two therapeutic areas.

[11] The drug discovery phase by which new medication candidates are discovered.

[12] Clinical testing up to commercializing of the drug.

3.2 Impact by geographic location

As we have seen earlier, the main points for growth in the drug development industry are located in developing countries, such as the BRIC (Brazil, Russia, India, China) countries. For CROs to gain more business opportunities, they need certain geographic presence to smoothen clinical trial management.

3.2.1 Large CROs

These companies have geographic presence to cover the whole world. Thus, having these facilities gives them a better coverage for managing big scale trials. In addition, this gives sponsors full coverage for the deployment of contracted clinical trials.

In this case, these market leaders take the risk to implant themselves in countries where business practices are different. Moreover, they have to adapt certain diversity to integrate at best to local cultures.

3.2.2 Medium CROs

Medium size CROs are located in fewer and more concentrated countries. They operate on a lower volume of activities, and do not need to expand as much as big CROs. Furthermore, they are in a position of followers, which makes them take less risk in regards to international presence.

Their infrastructures are compliant to perform a certain panel of tests. However, they are not as well equipped, as the larger CROs, for large-scale trials.

3.2.3 Small CROs

These companies are generally located in smaller cities, having fewer offices on a nation wide level. However, in regards to international presence, we may say that they are nonexistent. Their main focus would be local markets, rendering services on a national scale. These are minimal risk takers, as they develop in grounds they know.

3.3 Impact by service quality

Whenever a service is rendered to a client, this involves the quality of the data extracted, and the smoothened deployment of the service. The data gathered is essential for sponsor use, to know whether the medicinal properties of the molecules help patients in their daily struggles against diseases.

Consequently, each step of the CROs supply chain is involved. This starts from diagnostic view down to Investigator site [13]selection, to the testing, passing by the logistics portion, depending on the CROs product offering and the requirements of the pharmaceuticals. The CRO's supply chain becomes essential in the rolling-out of a service offering.

3.3.1 Large CROs

Since these companies have a wider range of products, and greater geographic reach, pharmaceuticals expect data to be the most significant for their R&D to blossom. Additionally, large CROs depend on this factor to drive growth in their business and attract more potential clients. Therefore, it increases notoriety and trust between CROs and pharmaceuticals.

3.3.2 Medium CROs

Service quality may help medium sized CROs to develop in notoriety and attract new business. If they are good at their local or international level, they may be companies to watch out for in the future.

One side, in which they may be competitive are the customized solutions. Since the market is tough, they will need to differentiate themselves to gain additional business. Therefore, the quality of their services needs to be optimal.

3.3.3 Small CROs

Since small CROs work on a local level, the results they will obtain will be specific to a region and not for international markets. The results achieved will touch a smaller population. Their technology and machinery maybe concentrated on specific targeted tests compared to the bigger companies.

3.4 Impact by therapeutic areas

Specialized therapeutic areas may attract additional business for CROs. If they are known to have performed good tests in a specific therapeutic area, this may give them the upper hand to acquire more business in that precise zone.

[13] The doctor who is in charge of monitoring the study for a specific site.

3.4.1 Large CROs

Indeed, large CROs cover more therapeutic areas. However, the volume they deal with is enormous. Little by little, these companies acquire smaller companies to gain specific expertize in relation to the growing demand by pharmaceuticals for more complex testing.

3.4.2 Medium CROs

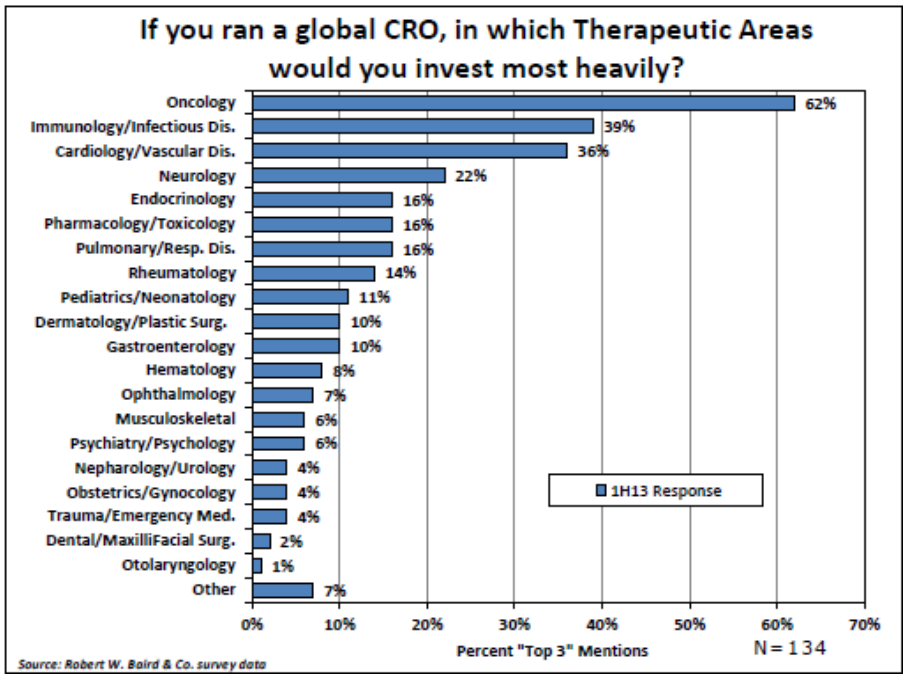
Since they cover less therapeutic areas, they need to specialize in a few to earn some notoriety in these specific areas for business to grow. One-way to do so are mergers and acquisitions, to expand in knowledge, and know-how.

3.4.3 Small CROs

These are companies with a lower range of products, but experts in the volume they treat. Since these companies are very specialized, they may be potential targets for larger companies to acquire.

Figure 5

Investments per therapeutic areas



Source: Robert W.Baird & Co. survey data

Figure 5 underlines data gathered from a survey made by the Baired group. This figure shows that the hundred thirty-four respondents think that CROs would need to invest

the most heavily in oncology, immunology, and cardiovascular equipment and expertize to attract more business. The aforementioned pharmaceuticals growth is mostly related to oncology trials. This graph shows that the trend for CROs is correlated to the one of pharmaceuticals.

3.5 Price Impact

One of the main challenges for any type of CRO is to be competitive on the pricing. Any company would go for the best CRO in regards to price and quality of the service to be performed.

Furthermore, price is correlated with timelines. If a service needs to be expedited it will indeed cost more for pharmaceuticals. Hence, drug development firms expect CROs to work in a timely manner, as the patent clock has already started.

3.5.1 Large CROs

For large CROs pricing is challenge, as amongst them, the rivalry is very tough. Even though these companies may rely on their economy of scales, the companies are faced with pricing difficulties to attract new business.

The CRO industry is difficult to benchmark, in regards to pricing, because services may vary across the different companies. Usually these big companies are sure shots for the management of clinical trial.

The main targeted clients for the large CROs are mainly big pharmaceuticals, big biotechnology firms, food companies, cigarette manufacturers, and medical instrument producers.

3.5.2 Medium CROs

For medium CROs, pricing is also puzzling. The differentiator for them would be the quality of their work. The fact of being more flexible to the client's needs may give them an advantage over bigger structures.

3.5.3 Small CROs

They may rely on their expertize on a local scale to attract clients. However, they have less economy of scale opportunities. Thus, having small business gives them even more flexibility to provide customized solutions for their clients. However, pricing may differ but remain higher than larger CROs for the same type of tests.

4. The CROs strategy

The CRO is known as the outsourced service provider for pharmaceuticals, biotechnology companies, food companies, cigarette manufacturers, and other medical equipment manufacturers. The main goal for these contract-oriented firms is to make more business in their core competencies, and generate more income. Most of these companies are publicly owned, thus shareholders interests are very important.

4.1 Macro Environment analysis (PESTEL)

It is essential for any company to analyze its external environment to be familiar with the different stakeholders that may influence a product or a company. The method that will be employed to evaluate this is denominated as a PESTEL (Political, Economic, Social, Technological, Environmental and Legal) analysis.

4.1.1 Political Factors

Since CROs usually operate in one specific country or in several countries, these firms are in need to be in line with local practices. However, for them to conduct their business, CROs need to be on top of any issue that may arise during the whole business process locally and internationally. Different countries have distinctive requirements in regards to clinical trials.

If we take the example of transport, we may identify that different countries have more requirements concerning importing and exporting blood genetic samples. These importing and exporting licenses have become a challenge to obtain in some countries, as the volume of testing has grown enormously during the past years.

4.1.2 Economic Factors

The CRO business is growing at a very fast pace. The demand from pharmaceuticals to outsource business is the key driver for growth in the industry. As seen previously, the main countries that interest the pharmaceuticals, at the moment, are located in the East. Furthermore, the growth for CROs will rely in these countries. The fact of adapting their business to these countries may undoubtedly improve growth.

4.1.3 Social Factors

The fact of being global and acting local should be a key point to adapt to local markets. This may be a driver for trust pertaining to cultural health consciousness. Furthermore, during trial management, it is critical to emphasize on safety related topics, because these can be factors that lead to discontinued clinical trials.

4.1.4 Technological Factors

As seen earlier, the R&D productivity for pharmaceuticals has been decreasing, giving room to outsourcing activities. On the CRO side, this brings in new business. Furthermore, CROs need to be inline with the latest testing instruments to give the sponsor a wider range of product support, and more quality oriented data. This may only be done with the latest methods, equipment, and IT infrastructures. This technological shift brings in more qualified manpower and leads to technological innovation.

4.1.5 Environmental Factors

The use of certain chemicals, and the disposing of other chemicals waste may result in heavy fines or penalties. This is why CROs need to be aware of their internal processes regarding waste management.

4.1.6 Legal factors

For CROs to operate, they need several accreditations by revising organs, such as the CAP (Certificate of American Pathologists). This type of organ reviews all process pertaining to laboratory practices. The accreditation has to be successfully accomplished for the laboratory to gain a 2-year right to exercise its testing activities, which is one of the core service solutions CROs provide. They also need to be in line with regulations relating to local and international safety laws.

For business to happen, it is critical for CROs to follow the “Good Laboratory Practices” set by the Organization for Economic Co-operation and Development (OECD), and re-enforced by part 58 title 21 of the Code of Federal Regulations, set by the FDA.

4.2 External Environment analysis (Michael Porter's 5 Forces)

Another tool that will help the macro-environment analysis would be the five forces enumerated by Michael Porter. This will provide us with an improved understanding of both the intensity in the CRO market, as well as the attractiveness in terms of profitability.

4.2.1 Threats of new entrants

In most cases, this industry has high barriers for new entrants. The fact of having large infrastructures with top of the line quality instruments creates this barrier. However, CROs are composed of different companies with different sizes performing in different therapeutic areas. However, the service offerings dictate the intensity of this market, and the possibility of new entrants to bloom in this fruitful market place.

4.2.2 Threat of substitutes

Depending on the service offerings, the threat of substitutes is considered low and almost inexistent. Since these are complex interconnected services, it is difficult and almost impossible to find specific clinical services from another service provider, which is not a CRO.

4.2.3 Rivalry among established firms

The competition on this market is harsh and may be viewed as high. Since this market may be regarded as a very fragmented one, the intense competition emerges from all levels. Once again, the price and quality factors of the services rendered become a key element in choosing the best-qualified CRO, in the matter of clinical trial management.

4.2.4 Negotiating power of buyers

The bargaining power of sponsors may be considered high. Since bids are performed to choose the most adequate service provider, this gives the buyer the best view of what each company could provide.

4.2.5 Bargaining power of suppliers

The haggling power of contractors can be considered moderate. On one hand we have the supplies providers that have little bargaining power that are managed by local procurement departments.

On another hand we have logistics contractors. Depending on the needs of the CROs, these suppliers may possess a certain bargaining power. Since the freight business is a volatile one, the negotiating power for this may have a substantial impact for CROs.

4.3 Micro Environment analysis

The micro environment analysis will be established by means of a SWOT analysis. Detailed in this table are the elements that point out the Strengths, Weaknesses, Opportunities, and Threats that affect the CROs.

Table 2

CRO SWOT Analysis

STRENGTH	WEAKNESS
Incease in R&D productivity Drive Time and Cost efficiency Improve ROI of R&D Strengthen pipelines Accelerate development cycles	No standard product Constant pressure by pharmaceuticals
OPPORTUNITIES	**THREATS**
Recruiting solutions Cost reduction by pharmaceuticals Post-Clinical trials Increase in R&D Budgets Partnerships Mergers and acquisitions Expertise	Tough competition Accreditation risk Weather Project cancellations Animal activists

4.3.1 Strengths

Looking at the Table 2, the Contract Research Organizations are one of the main contributors to a notable increase in R&D productivity. This may be verified by an increasing number of drugs approved by the FDA.

If 2010 was a the second lowest drug approved rate with only 21 new molecules approved, we may consider that R&D productivity the following year was soaring. In 2011, the FDA approved 35 new molecules. This shows that in one year, the number of molecules approved by the FDA grew significantly. We can also underline the statement that positive R&D productivity did boost pipelines for potential medication. Again, this is something attractive for pharmaceuticals.

Another attractive asset that a CRO proposes is to drive clinical trials in a timely manner, which reduces cost, and burdens for the pharmaceuticals. CROs posses the required expertize and the facilities to improve clinical trials. This avoids their customers to actually build new facilities and hire specific talents, which are time consuming and costly for the sponsor. Furthermore, this minimizes the cost of R&D, and improves the return on investment cost for R&D. Moreover, cost containment and increased R&D productivity upsurge the shareholder and stakeholder value for the pharmaceuticals. This clearly shows a win-win situation for both parties. On the pharmaceuticals side, this enhances their R&D productivity, their cost, and time factor, which result to potential new blockbuster products. On the CRO side, this brings in fresh business opportunities to enrich their activities.

As underlined earlier, time adds pressure in drug development. This is why optimizing in trial management, and other specific products deliverables become crucial. Thus, CROs are a key participant in the improvement and acceleration process of development cycles, going from the early to the late stages, of clinical trials.

4.3.2 Weaknesses

There are two main weaknesses that CROs are faced against. On one side we have standardization of products and on the other side is the pressure they have from pharmaceuticals to deliver the required work.

The fact of not having standard products adds difficulty to the service proposal to the sponsor. Requirements from one sponsor to another differ, and the CRO is in a position where he needs to meet all client expectations. This adds to operational challenges for the CROs to find the adequate resources to face the demanded requirements set by the clients.

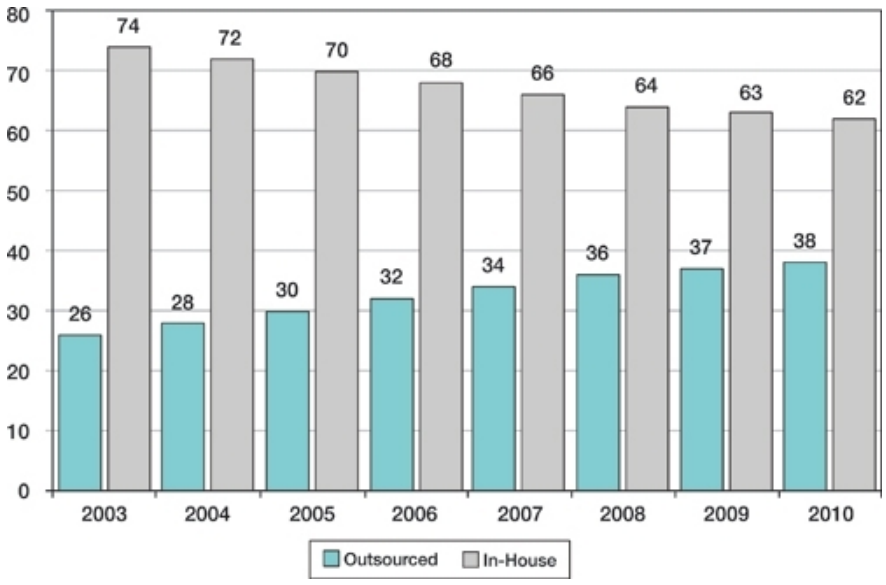
Since time is valuable in the pharmaceutical industry, this adds pressure to the CROs to deliver their work through tight timelines. This constantly brings re-adjustments to the operational structure of CROs. Furthermore, it is important for CROs to prioritize deliverables according to milestones set by the pharmaceuticals. These are challenges CROs accept to take. However, these types of commitments play a big role in the CROs reputation to deliver.

4.3.3 Opportunities

The CRO industry has a lot of room to grow. In regards to business opportunities, we can see that they are rising.

Figure 6

Global R&D Expenditures Outsourced 2003-2010 by percent



Sources: Contractpharma.com, march 2012

Figure 6 represents an increasing demand for outsourced services by pharmaceuticals. Between 2003 and 2010, the percentage of outsource services have gone up 12 percent. This shows trustworthiness to outsource more and more R&D activities to Contract Research Organizations.

Since CROs try constantly to innovate in new R&D solutions. Most of the big CRO companies really try to identify where the fundamental issues of clinical trials rely. This is why we can see a trend for a great number of big CROs to provide consultancy expertize. In the past years, researches from these companies have shown that one of the main issues in clinical trial management was patient recruitment, mostly in phases II[14] and III[15] of drug development. This is why the major players have taken that opportunity to develop clinical trial optimization tools.

[14] Once dosage of the drug is determined a larger pannel of patients will be tested (100 to 300 patients.)

[15] This phase includes drug testing for 300 to 3000 patients to detect the efficiency of the drug

These instruments provide the client with powerful knowledgebase. These databases give the clients incorporated data from past clinical trials, and puts together important data sources such as public data from the FDA and clinical trial.gov.. Additionally, these tools are oriented to enhance clinical site selections, increase performance predictions, integrate scenario-modeling tools, improve site activation sequencing, and give superior analysis trends.

As previously said, the CROs provide outsourced services for the pharmaceuticals. This gives the pharmaceuticals reliable data and services, without over-spending on new resources and infrastructures. Thus, lowering R&D costs for the pharmaceuticals, and brings new income for the CRO.

Another opportunity that can increase CROs earnings are post-approval trials in the phase IV of clinical trial management. These trials are anticipated to satisfy regulatory promises and to give additional knowledge about safety, and the effectiveness of the drug. The use of an outsourcing company can be more efficient, as they have the knowledge to enroll larger pool of individuals required in a challenging area of recruitment. Furthermore, the use of CROs can also serve as an advisor for pharmaceuticals to distribute their drugs more broadly and for a lengthier period of time. Moreover, companies wish to conduct phase IV trials to establish more effectiveness to surpass rivals.

More complex clinical trial require more investments from the sponsors, which leads to more business opportunities from growing R&D budgets.

Figure 7

R&D Budget of big Pharmaceutical Developers (2010 vs 2009)

Company	2010 R&D Budget ($B)	2009 R&D Budget ($B)	Change (%)
Merck	10.9	5.9	84.7
Roche	9.6	9.1	5.5
Pfizer	9.4	7.9	19.0
Novartis	9.1	7.5	13.3
GSK	6.9	6.4	7.8

Sources: Contractpharma.com, march 2012

Figure 7 gives us an idea of R&D budgets rocketing from one year to another. Most of these budgets are allocated in priority treatments for anti-cancer compounds, cardiovascular, and neurological diseases.

In the last couple of years, a trend of increasing number of strategic partnerships arose. These new models of collaboration are due to an industry seeking to improve stagnant productivity related challenges. For these partnerships to happen, both CROs and pharmaceuticals will have to align their efforts and strategies to enable true partnership.

These partnerships can be a win-win situation for both parties as the pharmaceutical company improves on project outcomes, and enhances productivity. On the CRO side, this adds precious long-term business. On a strategic business perspective, the CROs role evolves from a tactical service provider to an integrated development partner.

This involves the offering of larger portfolio services connecting to the sponsor's value chain. Thus giving the pharmaceutical the best customized solutions, a greater number of advantages throughout the value chain, and the fact of transforming fixed costs to variable costs.

For these partnerships to grow, it is mandatory for senior levels to be involved, as it is a bigger deal than a simple procurement service. Furthermore, senior management contribution from both parties is required to ensure the alignment of priorities and to facilitate decision-making on a strategic perspective.

Relationship management becomes vital for these types of deals to happen. The question of visibility for the CRO should be optimal, as it can change the approach, or help structure the approach. Thus, visibility can boost productivity, as the CRO can proactively put in place the needed resources and facilities accordingly.

Mergers and acquisitions becomes as well an opportunity to diversify product offerings. For example the merger of two small CROs namely Zeincro Group and Trial Masters merging to expand on geographical reach. On a bigger scale, we have the acquisition of Kendle by INC Research. This strategic acquisition by INC Research was done to diversify its expertize knowledge, its bigger geographical presence, and improve on operational service excellence.

Providing expertize and know how can be a non-negligible opportunity for CROs to gain more business. This service can give the pharmaceuticals more knowledge and gain in productivity in regards to specific medical practices. Furthermore, this approach would be more related to consulting and advising.

4.3.2 Threats

As specified before, the CRO industry is a fragmented market with a great number of players gathered all throughout the world. This makes the market tougher in relation to market share acquisition.

Since the service products offered to the sponsors are somehow similar, the real added value and differentiator of the services rely on the quality of the data gathered and the price. Thus, to remain on this market, CROs need to focus on the quality of their deliverables and have service prices corresponding to the market.

One big portion of the income of CROs comes from test related services. However, for these tests to occur, a number of accreditations are required concerning the testing methods and the quality of the instruments used. If a CRO doesn't comply to these accreditations, he may lose his license to perform laboratory related testing. Therefore, important business can be lost.

One of the most important accreditations a CRO must have is the CAP (College of American Pathologists) certification. This certification means that a laboratory meets the highest standards in quality for a laboratory. Consequently they oversee and inspect rigid quality control standards.

Like any other business, the weather may play a role in the business of CROs. Since a centralized laboratory performs most of the sample testing, the weather may impact the logistics of samples moving from one side of the globe to the other. This is why global CROs need good logistics coverage and contingency plans to avoid any weather related issues, such as volcano irruptions, or natural disasters.

Project cancellations may also be considered a threat to the CRO business. This means that the sponsor's molecule does not comply with patient safety requirements or other factors related to this. Furthermore, this drastically stopped a great number of the clinical trials in the past years. Moreover, CROs lost a great number business opportunity due to these cancellations.

In the last 10 years, a great number of animal protection activists protested in front of early development laboratories stating that CROs mistreat animals and that they kill them brutally. These types of protests affect the CROs business image and stab the reputation of these firms. This is why CROs communicate and specify the importance of having healthy animals. If an animal is healthy, the tests performed on him will deliver the most reliable data.

5. Dive into one of the most important CROs: Covance

This chapter will give you a better outlook regarding one of the leading companies in the industry. Throughout this chapter, we will get to know more on facts and figures, the types of services rendered, its mission, vision, objectives, business strategy, and its main competitors.

5.1 Company presentation

Covance Inc. (NYSE: CVD) is a public traded company based in Princeton, New Jersey, in the U.S.A. It is one of the world's biggest drug development services companies. This major player has over 11,000 employees located in 60 countries. Their main business evolves around the optimization lead for nonclinical, clinical and commercialization services. Covance has assisted pharmaceutical and biotechnology firms develop one-third of all prescription drugs in the today's market.

5.2 Facts and figures

In 2012, Covance reached its highest revenue ever of approximately 2.2 billion USD.

Figure 8

Covance Net revenues between 2012 vs 2011

INCOME STATEMENT DATA	2012[1]	2011[2]	CHANGE
(dollars in millions, except earnings per share amounts)			
Net Revenues			
Early Development	$ 869.5	$ 930.6	(6.6%)
Late-Stage Development	$ 1,311.1	$ 1,165.4	12.5%
Total Net Revenues	$ 2,180.6	$ 2,095.9	4.0%

Sources: Covance.com – annual report 2012

Figure 8 shows the evolution of Covance's growth from 2011 to 2012. We can see that earning have been split into two business segments. These two segments are the Early Development Services and Late-Stage Development Services. The business revenue in the early development dropped by 6.6 percent probably due to a lower demand of services, and a low "win" rate in bids for business. On the other hand, the main growth driver for Covance may be seen on the late stage development. This side of the business increased by 12.5 percent. The main component for this increase was booming Central Laboratory activities in phases II to phase IV.

5.3 Services

As mentioned on the previous page, Covance's service offerings are split between two segments namely Early Development Services and Late-Stage Development Services.

Table 3

Covance's service products

Covance's service products	
Early Development Services	**Type of Service**
Discovery support services	Immunology and polyclonal and monoclonal antibody services, metabolisme studies, pharmacokinetic screening, non- GLP toxicology, in vivo pharmacology, imaging services, biomarker services, and other support services
Preclinical services	Toxicology services, pharmaceutical chemistry, nutritional chemistry and other support services
Clinical pharmacology services	Clinical pharmacology services, and support services
Late-Stage Development services	**Type of Service**
Central laboratory services	Large scale testing,storage services, and other support services
Phase II to IV Clinical development	Clinical trial management for phase II to IV,
Market access services	Healthcare economics consulting services, risk evaluation and mitigation strategies specialty pharmacy services, and other support services

The services in Table 3 compile the types of services performed by a Covance. However, most of these services have corresponding support services, such as logistics teams, administrative teams, and technical teams.

5.4 Mission, Vision, Objectives, and Business strategy

This part will give us the picture of Covance's mission declaration, and how it will derive to its vision[16] statement. Furthermore, it will enlighten the objectives setting, down to the business strategy.

5.4.1 Mission

Our mission is to help our clients bring the miracles of medicine to market sooner.

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[16] The mission and the vision have been taken from the Covance annual report

5.4.2 Vision

Our vision is to be recognized by clients as the undisputed leader in providing drug development services and a trusted partner whose hallmarks are great people, high quality data, and a proven track record of integrating and streamlining development processes.

5.4.3 Objectives

Their objectives are to drive growth within the company, gain in market shares, and innovate the industry. The key factors for this will be determined by people excellence, process excellence, and client excellence.

5.4.4 Business strategy

Covance relies pharmaceuticals, biotechnology companies, and medical device industries to outsource more of their research and development arms, and a portion of marketing. The outsourcing will happen, according to Covance, due to cost containment pressure, limitations on internal capacity, a quicker way to develop drugs, research in multiple countries done simultaneously, and external expertize that customers lack.

The mains strategy is to provide high quality data in a timely manner that will support new drug approvals. Furthermore, long-term strategic partnerships with pharmaceuticals are a main focus. This is a source of new business that may last a great number of years.

Another effort is to expand by purchasing smaller specialized companies, or acquiring laboratories from clients to broaden service offerings and geographical presence.

5.5 Main competitors

There are many actors on this market ranging from small limited-service providers to global full-service providers.Covance's main competitors in the early stage segements are as follows : Charles River Laboratories International Inc., PPD, WIL Research Laboratories Inc., WuXi Pharma Tech Inc., and MPI Research Inc.
In the late stage development services, we find Quintiles Transnational Corp., PPD, Parexel International Corp, ICON plc, PRA International, inVentiv Health clinical, and Quest Diagnostic Inc..

Conclusion

Throughout this report, a number of key issues in the pharmaceutical industry have been underlined. Hence, we have seen poor efficiency in R&D from the pharmaceutical companies in regards to drug development in the past years.

The challenging business environment for the pharmaceuticals leads to a growing demand of outsourced products, regarding the R&D development arm of their business. Thus, this has led to the opening of business opportunities for Contract Research Organizations to assist in the development of solutions to boost the pharmaceutical industry. Furthermore, we may acknowledge the fact that CROs have brought cost effectiveness to their sponsors, improving the time invested in the consecution of clinical trials.

The Emerging Markets should be a prime target for pharmaceuticals, as opportunities seem to be abundant. The collaboration with CROs in these countries could be a solution regarding patient enrollment issues suffered by the pharmaceuticals.

Sponsors are urged to increase their participation in healthcare programs, in collaboration with Occidental governments, to embrace the markets of aging populations. This will undoubtedly take time, and may cause some compromises that the pharmaceuticals will have to absorb, one way or another.

We will be witnessing more mergers and acquisitions in years to come, from both pharmaceuticals as well as CROs, because it is one of the most efficient ways to grow and diversify product lines and product offerings. This would be a clever but costly approach to strengthen pipelines and gain in strategic positioning.

In the past year, we have seen partnerships flourish, and growing trust binding both pharmaceuticals as well as CROs. The study at hand illustrates that the collaboration between the aforementioned entities would result in a win-win situation. For CROs, we may observe increasing business opportunities where they are urged to provide their expertise, their facilities, and their global resources, necessary in conducting effective clinical trials on a worldwide scope. On the sponsor's side, one profits by means of obtaining valuable time, cost reduction, and in R&D productivity, with the intention of producing and delivering a new blockbuster drug, in a competitive manner.

We may also recognize a greater number of drugs approved by the FDA, as an indicator of increasing R&D productivity that was displayed between 2010 and 2011. This brought a significant increase of drugs approved by the FDA from 21 in 2010, to 35 in 2011.

Therefore, the conclusion of this report lies in positive dynamics relations between both sponsors and CROs. We may undoubtedly recognize the importance of the figure of the CRO in the life and perenity of a pharmaceutical company.

We will descry a greater implication of CROs in years to come, as R&D for the new molecules are coming to be progressively complex. This will require more specialized testing methods that CROs will be acquiring in coming years.

Recommendations

For the CRO industry to grow, my recommendation is that these companies invest in new technological instruments that may help the sponsors in the management of their daily challenges. These may refer to web tools that optimize data transfers, brining about a standard compatible with the sponsor's devices. This would be a swift solution for the obtainment of data in a secure fashion, with views of palliating any type of security breach. For this to come about, sponsors will also have to evolve by altering their own IT landscapes.

The use of cloud computing, which enables the user to access a network of remote servers on the internet, authorizes the sponsor to access, store, manage, and process data from a remote locations, by means of a laptop, a personal computer, a tablet, or a smartphone.

A higher-level use of social media could be another key to exponential growth for data collection. Presence on social platforms such as Facebook, Twitter, LinkedIn, among others, may be a way to recruit and inform potential patients on the types of studies that are being developed.

The development of clinical trial optimization tools could possibly be one of the greatest innovations that a CRO should focus on. These tools could be used to share knowledgebase, provide performance predictions, enhance site selections, create scenario modeling tools, and analyze up-and-coming trends. For a CRO, this would be equivalent to sharing its expertise with its clients, adopting a greater role of consultancy. The use of the CROs' past experiences, their specific recommendations, and their knowledge of FDA requirements is intended to reduce the time and costs invested by their clients.

The development of a vaster presence in the BRIC countries (Brazil, Russia, India, and China) is yet another way to reach out to these Emerging Markets. Since these populations are amongst the biggest in the world, this could provide more room for both patient recruitment as well as potential customers.

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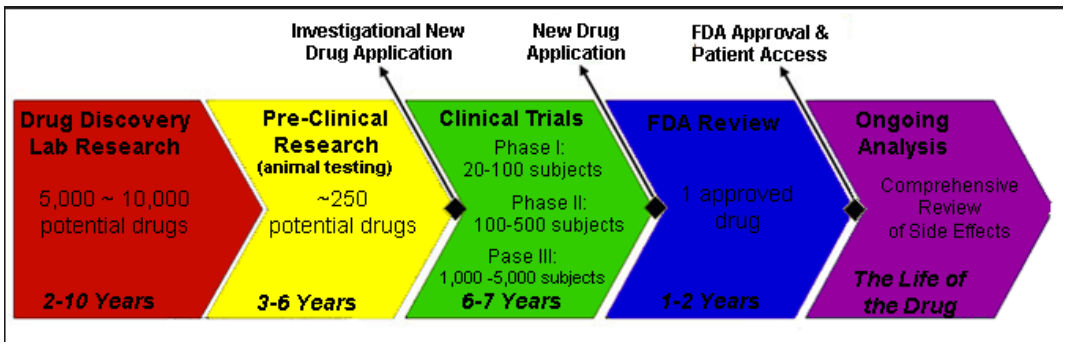
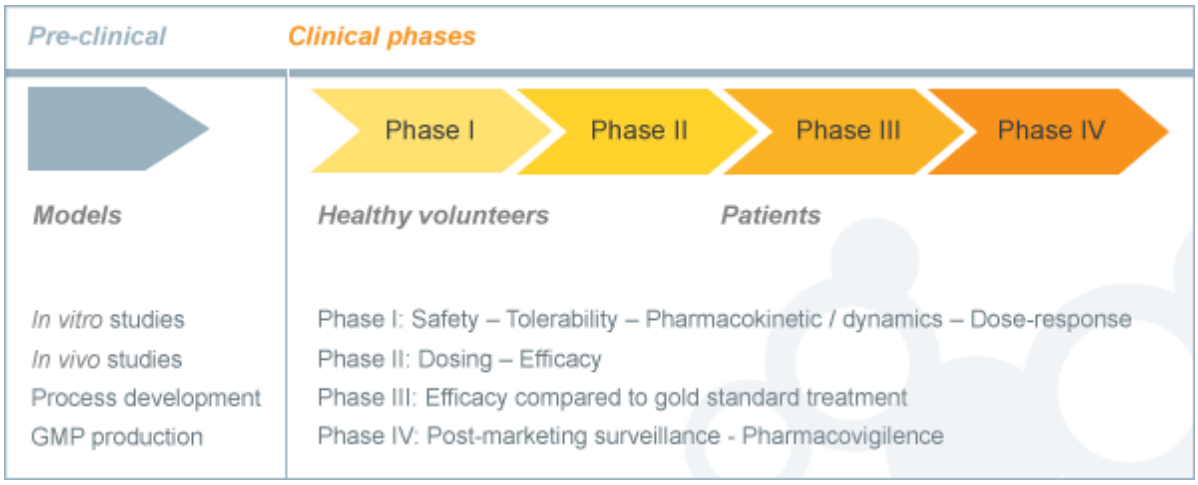
Annexe 1
FDA Approval Process



Source : http://cure4lupus.org/store/index.php?main_page=page&id=211&chapter=3

Annexe 2
Different phases in drug development



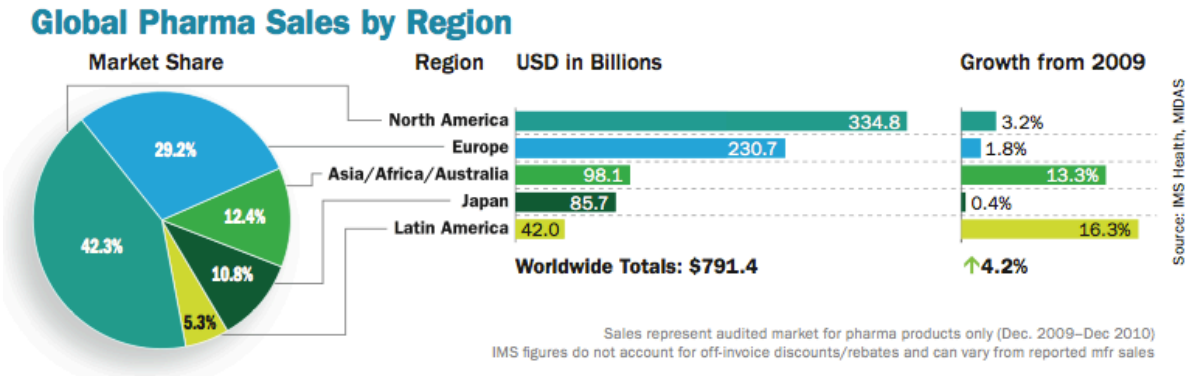
Source : www.geneuro.com

Annexe 3
Top 30 Pharmaceuticals in 2011

rank	Company	Country	2011 Rx Sales($ billions) Of biopharmaceutical products	2011 R&D spend($ billions)	Market share in %	Sales R&D Ratio
1	Pfizer	USA	57.70	9.11	9.5	15.79%
2	Novartis	Switzerland	54.00	9.10	8.9	16.85%
3	Merck & Co.	USA	41.30	8.47	6.8	20.50%
4	Sanofi	France	37.00	6.01	6.1	16.24%
5	Roche	Switzerland	34.90	7.86	5.7	22.53%
6	GlaxoSmithKline	UK	34.40	5.82	5.6	16.92%
7	AstraZeneca	UK	33.60	5.03	5.5	14.98%
8	Johnson & Johnson	USA	24.40	5.14	4.0	21.06%
9	Abbott	USA	22.40	4.13	3.7	18.43%
10	Eli Lilly	USA	21.90	5.02	3.6	22.92%
11	Bristol-Myers Squibb	USA	21.20	3.80	3.5	17.92%
12	Teva	Israel	16.70	1.08	2.7	6.47%
13	Amgen	USA	15.30	3.17	2.5	20.70%
14	Takeda	Japan	15.20	3.47	2.5	22.80%
15	Boehringer Ingelheim	Germany	13.80	3.23	2.3	23.41%
16	Bayer	Germany	12.80	1.98	2.1	15.46%
17	Daiichi Sankyo	Japan	11.60	2.33	1.9	20.10%
18	Novo Nordisk	Denmark	11.50	1.66	1.9	14.45%
19	Astellas	Japan	11.40	2.61	1.9	22.87%
20	Gilead Sciences	USA	8.10	1.23	1.3	15.17%
21	Otsuka	Japan	7.40	1.97	1.2	26.68%
22	Merck KGaA	Germany	7.20	1.58	1.2	21.90%
23	Baxter	USA	6.10	0.95	1.0	15.51%
24	Mylan	USA	5.50	0.29	0.9	5.35%
25	Servier	France	5.00	1.26	0.8	25.10%
26	Mitsubishi Tanabe	Japan	4.70	0.79	0.8	16.77%
27	Celgene	USA	4.70	1.60	0.8	34.04%
28	CSL	Australia	4.50	0.35	0.7	7.76%
29	Allergan	USA	4.40	0.90	0.7	20.50%
30	Forest	USA	4.20	0.72	0.7	17.02%

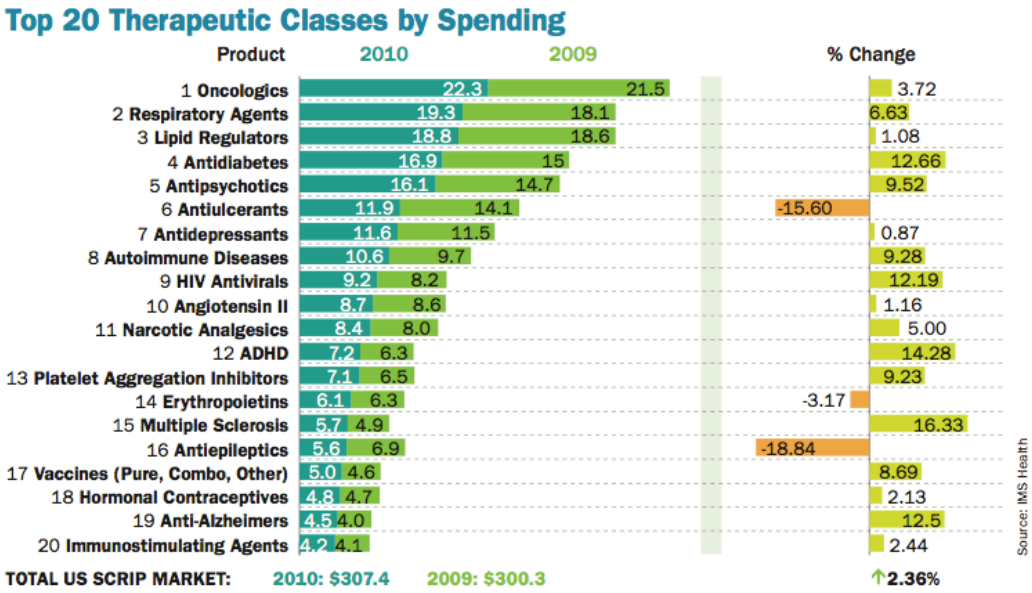
Source : http://www.currentpartnering.com/insight/top-50-pharma/

Annexe 4
Global Pharma Sales by Region in 2010



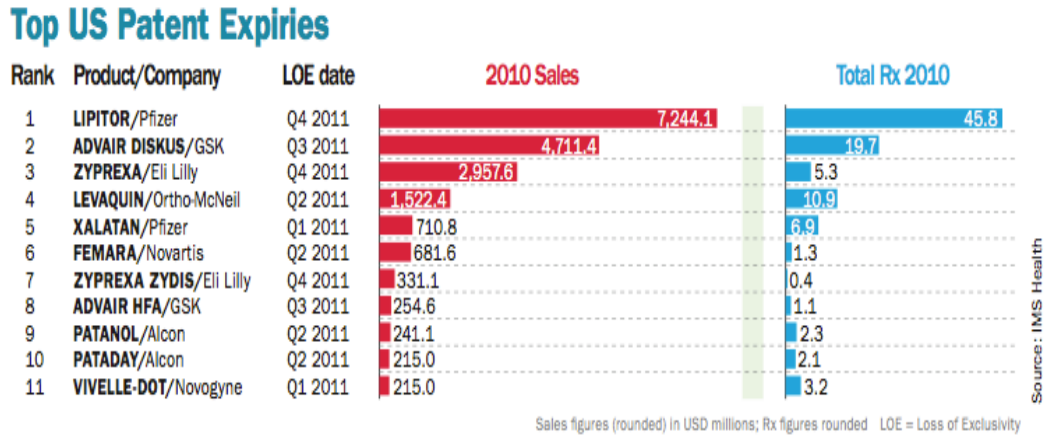
source : http://thebigredbiotechblog.typepad.com/files/top-pharama-companies-2011-rpt.pdf

Annexe 5
Top 20 Therapeutic Classes by Spending



Source : http://thebigredbiotechblog.typepad.com/files/top-pharama-companies-2011-rpt.pdf

Annexe 6
Top US Patent Expiries



Source : http://thebigredbiotechblog.typepad.com/files/top-pharama-companies-2011-rpt.pdf